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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,722	02/04/2002	Brent C. Gerberding	10527-391001 / 01-454	7186

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EXAMINER

SWEET, THOMAS

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/09/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/067,722

Applicant(s)

GERBERDING, BRENT C.

Examiner

Thomas J Sweet

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-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 34-54 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-5,7,9,11,12-14,15,18-22,24,26,28-31 and 33-40 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments, see page 7, the last 2 paragraphs, filed 6/13/03, with respect to the rejection(s) of claim(s) 6, 8, 16, 17, 23, 25 and 41-47 under 35 USC § 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art reference.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "sheath" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 14-21, 23-26, 29-45 and 47-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Sgro (US 606312). Sgro discloses medical device (fig. 1) comprising a catheter (3), an expandable balloon (4), an expandable endoprosthesis (stent, 5) positioned on the balloon and an expandable sleeve (6) extending over an end of the endoprosthesis and a portion of the balloon adjacent the endoprosthesis wherein the sleeve is configured to separate (9) into a plurality of detached portions (6a, 6 and 6b) along separation portions extending along a portion of the circumference of the sleeve.

Regarding claims 6-8, 23-25, 48-49 and 52-53, the catheter comprising a balloon comprises tapered (sleeve) portions (4a and 4b) and the sleeve attaches to these portions (balloon and catheter).

Regarding claims 11-12 and 21, Column 5, lines 5-10.

Regarding claims 14, 15 and 26, the sleeve is perforated defining lateral openings.

Regarding claims 16-17 and 50-51, the sleeve inherently is configured to separate at a predetermined level of balloon expansion which would be smaller than the diameter of the vessel. Otherwise the stent could not be left in the vessel. There is also a pressure associated with this predetermined expansion and thereby controlled by the physician using pump (7) with a pressure gauge.

Regarding claim 19, in the undeployed configuration the endoprosthesis is embedded (surrounded) in the sleeve.

Regarding claim 31, the separating portions are asymmetrically positioned along the catheter, since the balloon is asymmetrically positioned at the end of the catheter.

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Regarding claims 35-40, this is the inherent method of implant the medical device. The method would sequentially include the steps of positioning the medical device in the body lumen, expanding the balloon there by sequentially separating the sleeve into three portions thereby the outer surface of the sleeve defines an opening (at 9a and/or 9b) which would be aligned with an opening (lumen) defined by a body lumen.

Regarding claim 43, may be a self-expanding prosthesis (col 5, line 14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sgro in view of Bigus et al. Sgro discloses a medical device as discussed above. However, Sgro remains silent as to whether the sleeve comprises a therapeutic agent. It is well known in the art of endoprosthesis delivery systems to include medicament on or in a deployment sleeve for the purpose of treating the area of implantation as for example taught by Bigus et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include medicament in or on the sleeve of Sgro, because it is well known in the art to do so to treat the implanted area.

Claims 27, 28, 46 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sgro. Sgro discloses a medical device as discussed above.

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With regard to claims 27 and 54, Sgro does not disclose a separation portion having a thickness less than a thickness of the balloon. The thickness of the Sgro balloon and sleeve appear to be substantially the same thickness. However, it is within the skill of one of ordinary skill in the art to vary the thickness of the balloon and/or sleeve as a matter of mere design choice, so that the sleeve would be thinner than the balloon. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the sleeve of Sgro thinner (and thereby the separation portion) than the balloon and as such the modification would have been considered a mere design choice which fails to patentably distinguish over the prior art of Sgro.

With regard to claim 28, Sgro remains silent as to whether the separation portion is over the stent. Applicant has not disclosed that having the separation portion over the stent solves any stated problem or is for any particular purpose. Moreover, it appears that the sleeve would perform equally well with the separation portion anywhere over the balloon. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modified the sleeve of Sgro to have the separation portion over the stent because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Sgro.

With regard to claim 46, Sgro remains silent as to whether the medical device includes a sheath over the sleeve. It is well known in the art of endoprosthesis delivery systems to include sheath over a sleeve for the purpose of protecting the sleeve and help guide the catheter during the insertion procedure. It would have been obvious to one of ordinary skill in the art at the time

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the invention was made to include sheath over a sleeve of Sgro, because it is well known in the art to do so to protecting the sleeve and help guide the catheter during the insertion procedure.

Allowable Subject Matter

Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is (703) 308-4018.

The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

tjs


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